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A Biotechnology Notes

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Biotechnology Notes, a compilation of agency activities, news events, and upcoming meetings, is prepared for members of the U.S. Department of Agriculture's (USDA) Committee on Biotechnology in Agriculture (CBA) by USDA's Office of Agricultural Biotechnology (OAB).

INSIDE USDA

TRANSGENIC FISH EXPERIMENT GETS THE GREEN LIGHT

Candide, the 18th century French seeker of wisdom immortalized by Voltaire, and today's agricultural researcher, have more in common than one might suspect: both are credited with having inquisitive minds and each has been known to devote entire lifetimes to the pursuit of knowledge. The recently approved experiment with transgenic carp that will take place at Alabama's Agricultural Experiment Station at Auburn University is an example of the same attributes that have driven men and women throughout the ages down the path of discovery and enlightenment.

The outdoor phase of the Auburn project will begin in early 1991, pending USDA's inspection of a new fish hatchery facility and new outdoor research ponds. Nine transgenic carp will be artificially spawned indoors. The carp contain a growth hormone gene from rainbow trout. A total of 50,000 of the fry -- half transgenic, half controls -- will then be stocked in 10 new outdoor research ponds. After about 3 months, the number of fish will be reduced to 3,000 and marked for identification. Researchers will study the fingerlings until they are about 15 months of age and end the experiment before the fish reach sexual maturity.

USDA's Cooperative State Research Service (CSRS) funded the experiment and according to CSRS Administrator John Patrick Jordan, "The research using carp as a model will further basic knowledge and experience in the use of rDNA to develop improved fish genetic lines, such as catfish for aquaculture production." He added that carp is being used as a research model, much like the tobacco plant is often used a model in plant research studies.

Scientists hope to learn how the trout growth hormone gene effects the reproductive capacity of brood carp and determine whether offspring inherit the gene and the effects of the gene on the survival, growth rate, and behavior of the offspring. Anyone wishing to obtain a copy of the environmental assessment and its "Finding of No Significant Impact" may call the Office of Agricultural Biotechnology at 202-447-9165.

ABRAC MEETS IN CHARLESTON, SC

Members of USDA's Agricultural Biotechnology Research Advisory Committee (ABRAC) met November 26-27 in Charleston, SC. ABRAC Executive Secretary, Alvin Young, traced the evolution of the ABRAC's major effort, draft USDA research guidelines, up to their current form in which principles of field testing are delineated from implementation issues. He said the principles will be published first in the Federal Register, as soon as the Office of Management and Budget has completed its review and other Federal agencies have had an opportunity to review and comment on the guidelines.

Other meeting highlights included a summary of public comments on the Office of Science and Technology Policy's scope document, cooperative activities between ABRAC and the National Biological Impact Assessment Program, and a request from the National Association of State Universities and Land Grant Colleges for assistance in preparing petitions to regulatory agencies.

NEW USDA-JAPAN AGREEMENT

An interagency group is planning cooperative activities on biotechnology with Japan under the U.S.-Japan Agreement on Cooperation in Research and Development in Science and Technology. Areas of study may include bioprocessing and genomic mapping. According to the agreement, both the United States and Japan would have equal access to all publicly funded research in both countries, and cooperative activities would be open to academic, governmental, and private researchers.

BIOTECH COUNCIL MEETING HIGHLIGHTS EPA AND OECD ACTIVITIES

At the October 30 meeting of USDA's Biotechnology Council, Larry Zeph of the Environmental Protection Agency (EPA), Terry Medley of USDA's Animal and Plant Health Inspection Service (APHIS), and Sue Tolin, professor at Virginia Polytechnic Institute and State University, gave updates on recent activities. Zeph said EPA has reviewed 75 product applications to date, most of them for microbial pesticides. Eight products have been field tested. He explained that an experimental use permit is required for any field test covering more than 10 acres, whether the organism is genetically modified or not; field tests under 10 acres only require a review if the organism was genetically modified.

Medley and Tolin reported on a meeting of the plenary session of the Group of National Experts on Biosafety in Biotechnology of the Organization of Economic Cooperation and Development (OECD), October 22-25, in Paris, France. A working group on food safety was established that will look at the issues involving the development and commercialization of novel foods produced with biotechnology. The chair will be Frank Young, current head of the U.S. delegation and Deputy Assistant Secretary for Health at the Department of Health and Human Services.

The document "Good Industrial Large-Scale Practices" was reviewed and appears close to finalization. It applies to low-risk microorganisms appropriate for industrial production with minimum containment and control procedures.

A working group on safety assessment agreed to initiate a project that will examine the scientific issues related to moving small field tests to large-scale field research and to analyze results of prior field releases.

USDA SCIENTIST OF THE YEAR AWARDS

On November 7, USDA's ARS recognized outstanding research scientists for 1990 at a ceremony held at USDA headquarters in Washington, DC. The distinguished scientist award was given to Norman Cheville, Research Leader, at ARS's National Animal Disease Center, Ames, Iowa for "pioneering research advancing the understanding of animal disease processes at the cellular and molecular levels."

EDITORIALLY SPEAKING

In a recent editorial that appeared in <u>Genetic Enqineering News</u> (Regulatory Issues column, September 1990), Terry Medley, director of APHIS's Biotechnology, Biologics and Environmental Protection (BBEP) staff, discussed the history, philosophy, and current trends in biotechnology regulation. In particular he stressed the importance of maintaining a regulatory structure based on risk rather than process and developing regulations that "protect agriculture and the environment while facilitating safe technology transfer." In this regard, Medley also examined a similar aim of the Office of Science and Technology Policy's scope document on the Federal regulatory framework and called for more public education programs focusing on biotechnology. Copies of the editorial may be obtained by calling BBEP at 301-436-7602.

APHIS PLANS WORKSHOPS ON LARGE-SCALE FIELD TESTS

The success of small-scale field tests over the last few years has paved the way for the next phase of outdoor testing: large-scale plantings of transgenic crops. To ensure USDA's permit review process and preparation of environmental assessments provide adequate safeguards, APHIS is holding three workshops. The results of these workshops will be used to develop permit review procedures and requirements. For more information, call BBEP at 301-436-7602.

NEWS AROUND THE COUNTRY (AND THE WORLD)

CGIAR TO RECEIVE MORE FUNDING; NEW CENTERS TO BE ADDED

At its annual meeting October 29-November 2 in Washington, DC, the CGIAR (Consultative Group on International Agricultural Research) agreed to increase funding by \$10 million for 1991 to \$244 million. It also said natural resource management would be incorporated into its research agenda and that new centers will be added to the network. These centers will focus on research of forestry/agroforestry, irrigation management, banana and plantains as major food staples, and fisheries.

The CGIAR is an association of more than 40 governments, international organizations, and private foundations that support ag research and development around the world. Major contributors for 1990 were the United States, Japan, Canada, the United Kingdom, and Germany.

NEW STATE SURVEY OUT

The Industrial Biotechnology Association's (IBA) latest survey of state government legislation on biotechnology is now available. Nine issues concerning biotechnology are tracked in the survey, including those pertaining to agricultural research and environmental release. See page 8 of this newsletter for a quick scan at what the states are doing on the legislative front. To obtain a copy of the report, call the IBA at 202-857-0244.

HAVING A POSITIVE ATTITUDE

This poll was conducted by <u>AqBiotechnology News</u> magazine and shows most agricultural researchers and executives (75 percent) were either "positive" or "very positive" about the future of the industry. University sources expressed similar optimism. Associations, however, reported a slightly more negative outlook.

When asked about major problems facing the industry today, most cited public perceptions, regulations, and financing. Copies of the report cost \$65 and may be ordered from AgBiotechnology News, P.O. Box 7, Cedar Falls, Iowa 50613.

BREAKING NEW GROUND

On a lovely autumn day in mid-November, beneath gold-leafed maples and loblolly pines, the State of North Carolina held a ground breaking ceremony and reception for its new Biotechnology Center. The \$5.5 million structure will house a program-management center, conference rooms, education center, and a large library open to the public. The Center funds and supports research at universities and small companies. USDA, the State of North Carolina, private industry, and the Center helped to fund construction. Keynote speaker Governor Jim Martin said the Center is "the catalyst for the work of hundreds of researchers, entrepreneurs, government agencies, and educators in the field. . . this Center is the reason why we have a growing statewide biotechnology community and a statewide biotechnology initiative."

UP ON THE HILL: A LOOK BACK AT THE 101ST CONGRESS

The IBA recently prepared a report summarizing legislation enacted by the last Congress that affects biotechnology. The issues covered range from agricultural and biomedical biotechnology to patent office funding and research and experimentation tax credits. The report notes that the 1990 farm bill (S. 2830) creates a National Competitive Research Initiative for funding in several "high priority" areas including, but not limited to: plant systems, molecular and cellular genetics, and plant and microbial biotechnology; plant-pest interactions and biocontrol systems; the molecular basis of animal reproduction, growth, disease, and health; and natural resource and environmental quality and management.

Another provision creates a Biotechnology Risk Assessment Research Program which authorizes a competitive research grant program to fund health and environmental assessment research. To receive a copy of "A Comprehensive Summary of Legislation Affecting the Biotechnology Industry," call the IBA at 202-857-0244.

IN CASE YOU WEREN'T THERE

• "U.S. and Asian Pacific Biotech Conference '90: Collaboration and Commercialization" was the title of an international meeting held October 21-23 in The Woodlands, Texas. The purpose was to focus on potential research and development linkages between the United States and Asian and Pacific nations. Overviews were presented of biotechnology activities in Hong Kong, Japan, Korea,

Singapore, Taiwan, and Thailand. Other sessions looked at technology transfer, and financing strategies. During the meeting, the first Cynthia and George Mitchell International Award for Biotechnology was presented to Dr. K. T. Li of Taiwan and Dr. David Baltimore, President of Rockefeller University. Robert Mosbacker, Secretary of Commerce, addressed the group stressing the opportunities for growth in the biotech industry.

- The EPA sponsored a meeting in Annapolis, Md., November 6-7 entitled "Regulatory Considerations of Pesticidal Transgenic Plants." Topics discussed included the interaction of molecular biology and plant breeding during product development, risk assessment concerns, and draft data requirements.
- The "International Symposium on the Biosafety Results of Field Tests of Genetically Modified Plants and Microorganisms" met November 27-30, in Kiawah Island, SC. Charles Hess, USDA's Assistant Secretary for Science and Education, gave the welcoming address and announced the signing of the 1990 Farm Bill, which includes funding for biotechnology risk assessment research. He called for more discussion about the benefits and risks of biotechnology and said the availability of scientific information along with a sound regulatory structure should reassure the public that biotechnology research is being conducted safely.

Thirty scientific experts from around the world presented their biosafety research findings, and none reported any unusual, novel, or unpredictable behavior of genetically engineered organisms. In the opinion of one attendee, Horst Fischer, an analyst with Germany's Environmental Protection Agency, this finding, coupled with the diversity of speakers from industry, academia, and government, formed the crux of the symposium.

There were six panels, each composed of five experts in biotechnology. The panel topics included: biosafety implications from contained experiments; biosafety protocol development for field testing; biosafety review and release certification; research plot establishment, monitoring, and termination; post-termination evaluation of biosafety data; and issues beyond the small plot.

Proceedings of the meeting will be available March 15, 1991. To receive a copy, call 202-401-4892.

NEW PUBLICATIONS

Immunochemical Methods for Environmental Analysis. Edited by Jeanette M. Von Emon, EPA, and Ralph O. Mumma, Pennsylvania State University. Developed from a symposium held at the 198th National Meeting of the American Chemical Society, September 1989. ACS Symposium Series No. 442. \$49.95. Published November 1990. To order call 800-ACS-5558.

- "Biotechnologies and Food: A Summary of Major Issues Regarding Safety Assurance." Reprints of the full report should now be available and may be obtained by calling the International Food Biotechnology Council at 202-659-0789.
- "Emerging Biotechnologies in Agriculture: Issues and Policies." Progress Report IX. November 1990. Prepared by the National Association of State Universities and Land-Grant Colleges' Committee on Biotechnology. To order a copy, write to Judy Kite, Office of the Dean for Research, 1022 McCarty Hall, University of Florida, Gainesville, Fla. 32611.
- "Plant Germplasm: Improving Data for Management Decisions (Volume 1) and A Data Collection Framework and Questionnaire (Volume 2)." Prepared by the U.S. General Accounting Office. October 1990. For ordering information (the first five copies of each report are free), write to U.S. General Accounting Office, P.O. Box 6015, Gaithersburg, MD 20877; or call 202-275-6241.
- Surface Reactive Peptides and Polymers: Discovery and Commercialization. Edited by C. Steven Sikes and A. P. Wheeler. ACS Symposium Series No. 444. November 1990. \$69.95. To order call 1-800-ACS-5558.
- "Reducing Risk: Setting Priorities and Strategies for Environmental Protection." Prepared by EPA's Science Advisory Board, Relative Risk Reduction Strategies Committee. September 1990. To obtain a copy, write to The Science Advisory Board (A-101), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.

UPCOMING MEETINGS

1991

Jan. 6-9: BioEast '91. Washington, DC. 212-996-5679.

Jan. 6-9: The Second U.S.-Japan Symposium on Biotechnology: Control of Biological Processes. St. Petersburg, Fla. Sponsored by Tampa Bay Research Institute. For more information call 813-576-6675.

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The Industrial Biotechnology Association

1990 State Legislative Initiatives in Biotechnology

